Health Canada
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REVIEW OF HEALTH CANADA'S POLICIES CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS

EVALUATION OF FOOD FORTIFICATION APPROACHES BACKGROUND PAPER

FOOD DIRECTORATE, HEALTH PROTECTION BRANCH

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This document was prepared by: Mary L'Abbé, Sarah Conly, Kevin Cockell and Nora Lee, Bureau of Nutritional Sciences, Food Directorate, Health Protection Branch, Health Canada.

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FOOD DIRECTORATE REVIEW OF HEALTH CANADA'S POLICIES CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS

EVALUATION OF FOOD FORTIFICATION APPROACHES - BACKGROUND PAPER

1. INTRODUCTION AND PURPOSE OF THIS POLICY REVIEW

In January 1998, a comprehensive review of Health Canada's policies concerning the addition of vitamin and mineral nutrients to foods was announced. Canada currently adheres to the international *Codex General Principles for the Addition of Essential Nutrients to Foods*. Addition of vitamins and minerals to foods is controlled by the Food and Drug Regulations in accordance with these principles. The present regulatory controls are considered to be overly restrictive by some sectors of the food industry and consumers. These sectors would like to satisfy consumer demand for products available in the United States and other countries where there are less restrictive controls on the addition of vitamins and minerals to foods. They are also seeking a relaxation in the current controls to increase Canadian business opportunities. As part of Regulatory Review, Health Canada agreed to conduct a review of its policies taking into account the public health role of nutrient addition to foods, consumer needs and industry concerns.

2. OVERALL PLAN FOR THE POLICY REVIEW AND ACCOMPLISHMENTS TO DATE

The length of the policy review was projected to be 18 months from its announcement in January 1998 (Appendix A). Several phases in the policy review have already been completed. A Government Working Group (WG) was formed, composed of representatives from various government groups whose work is impacted by this policy (e.g. Food and Therapeutic Products Programs in the Health Protection Branch of Health Canada, Health Promotion and Programs Branch of Health Canada, and the Canadian Food Inspection Agency) (Appendix B).

An External Advisory Panel (EAP) was established from nominations obtained from the food industry, consumers, disease and health associations, health professionals, academia and government. The 12 members were selected to represent a balanced mix of disciplines, skill sets, perspectives and geographical representation (Appendix C). The EAP has provided ongoing expertise and advice during all phases of this policy review.

On March 27, 1998, a one day Consultation Workshop was held to consult with a broad cross-section of stakeholders to help identify issues relating to this policy initiative. Approximately 85 participants attended the workshop, with balanced representation from disease-based and health organizations, dietetic and other health professionals, industry, consumers, academia and

governments. The first steps taken at the meeting were to develop guiding principles for the review and then to identify the issues of concern. The issues raised fell within such diverse areas as public health, safety, consumer choice and availability, and trade and competitiveness. Not only did we succeed with the objectives of the meeting, but the consultation also succeeded in raising the awareness of all issues in all groups. Participants commented that the balanced representation allowed them to have a greater appreciation for the breadth of the issues and diversity of the groups involved.

Subsequently the External Advisory Panel (EAP) and Government Working Group (WG) met for two days in June and again for two days in September to continue work on the policy review. The objective of these meetings was to incorporate as many of the issues as possible that were raised at the March Consultation Workshop into the development of potential policy option scenarios. The Guiding Principles were reviewed and collapsed into statements of objectives and outcomes for food fortification policies. The issues raised in March were reviewed, analysed and the key messages used to develop criteria by which policy options (food fortification approaches) could be assessed.

A series of food fortification approaches was developed covering the full range of possible reasons for adding vitamins and minerals to foods. They range from the most restrictive to the free addition of vitamins and minerals to foods with little government involvement. This series of food fortification approaches, which describe reasons for adding vitamins and minerals to foods, has been considered and evaluated by the EAP and WG. These potential approaches and their analysis are presented in this document and will form the basis for the discussions at the November Consultation Workshop.

3. OBJECTIVE OF CONSULTATION WORKSHOP - NOVEMBER 23-25, 1998

The objective of this workshop is to obtain input from a broad cross-section of stakeholders concerning various food fortification approaches, or reasons for adding vitamins and minerals to foods. The Food Directorate will use this consultation workshop to obtain stakeholder's input and comments on the food fortification approaches being considered to help in making the final decision regarding the new policy.

The purpose of this paper is to provide all participants at the workshop with an overview of the development of criteria for assessing potential food fortification approaches, and to present the approaches, along with the analysis of the approaches that was done by the EAP and WG at their June and September meetings. We hope that this material will assist you in your evaluation of this complex topic.

4. BACKGROUND, HISTORY AND CONTEXT

The following section was taken (with some sections updated) from the Background Paper to Issues Identification for the March 27, 1998 Consultation Workshop.[1] It provides a review of the background, history and context of food fortification policies.

A. What Roles do Policies on the Addition of Vitamins and Minerals to Foods Serve?

There are a number of reasons why governments have policies concerning the addition of nutrients to foods. They provide a uniform set of principles which when applied ensures a rational and consistent approach to the addition of nutrients to foods. They can be used to achieve the public health objectives of maintaining and improving the over-all nutritional quality of the national food supply and of addressing the nutritional needs of specific population sub-groups. Their application can avoid random nutrient addition which could lead to both excessive and inadequate intakes and create nutrient imbalances.

Codex[2] states that the General Principles for the Addition of Essential Nutrients to Foods are intended:

- To provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods.
- To establish a uniform set of principles for the rational addition of nutrients to foods.
- To maintain or improve the nutritional quality of foods.
- To prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.
- To facilitate acceptance in international trade of foods which contain added essential nutrients.

[1] Health Canada, Health Protection Branch. Review of Health Canada's Policies Concerning the Addition of Vitamins and Minerals to Foods, Background Paper to Issues Identification. March 27, 1998. (Available from the Nutrition Evaluation Division, Food Directorate, HPB or on the Health Canada website: <<*www.hc-sc.gc.ca/datahpb/datafood*>> go to Nutritional Sciences/Regulation of Nutritional Quality of Food/Review of HC Policies Concerning the Addition of Vitamins and Minerals to Foods).

[2] Joint FAO/WHO Food Standards Programme, Codex Alimentarius, Volume 4, Rome, 1994, p.9.

B. Federal Regulatory Policy

The objective of Federal Regulatory Policy[3] is "to ensure that government regulatory powers result in the greatest net benefit to Canadian society. Canadians view health, safety, the quality of the environment and economic and social well-being as important concerns. The government's regulatory activity in these areas is part of its responsibility to serve the public interest". Federal Regulatory Agencies must ensure that they have analysed the problem or risk and that regulation is justified. They must provide timely and thorough consultation with interested parties and ensure that: benefits outweigh the costs; adverse impacts on the economy and employment are minimized; and intergovernmental agreements are respected. The present policy review will be conducted accordingly.

C. Current Context

I) Canadian

i) History

When synthetic vitamins and vitamin concentrates first became available, there were no restrictions on their addition to unstandardized foods in Canada. Regulations were introduced in 1941 to set minimum levels for some added vitamins in foods to prevent the consumer from being defrauded. In 1949, maximum levels were specified to prevent exposure to excessive amounts. Unstandardized foods could contain any added nutrients within the limits stated in the Regulations. Standardized foods whose identity and composition are controlled by the Food and Drug Regulations (e.g. flour, bread, milk, salt) could not contain added vitamins and minerals unless they were specifically permitted in the standard. Iodization of salt was made mandatory in 1949 and vitamin D addition to evaporated and dried milks was permitted in 1950. Enrichment of flour was introduced in 1953 following the entry of Newfoundland into Confederation.

Experiences with vitamin D initiated further changes to the regulations of nutrient addition. During the 1940s and 50s, any unstandardized food could be fortified with vitamin D at a minimum level of 400 IU in a reasonable daily intake. A maximum of 800 IU per reasonable daily intake was established in 1949. A range of vitamin D-fortified products came onto the market including fruit drinks, biscuits and cocoa mixes. A survey of children in Ontario in 1963 showed that many infants and young children were receiving over 2000 IU per day, 2/3 from supplements. Older children (8 years and over) could easily be exposed to 4000 IU. At the same time, rickets continued to be a problem. The appearance of a number of cases of idiopathic hypercalcemia of infancy, mostly in Great Britain in the mid 1950s to early 60s, thought to be related to high intakes of vitamin D drew attention to this situation. When addition of vitamin D to foods was restricted in the UK in an effort to reduce the risk, the rate of idiopathic hypercalcemia of infancy declined. In 1964, action was taken to remove vitamin D from unstandardized foods in Canada. This was part of broader regulations that restricted the addition of vitamins, minerals and amino acids to only those foods identified in the

[3] Federal Regulatory Policy, Treasury Board of Canada Secretariat, 1995.

Regulations (Part D). The restrictions on vitamin D addition resulted in an increase in rickets[4] because a fundamental principle of food fortification, the selection of an appropriate vehicle to reach the target population, had been overlooked. The addition of vitamin D to fluid milk in the late 1960's and early 1970's was successful in virtually eliminating rickets as a public health problem in Canada. In 1975, this fortification was made mandatory to ensure its universal application.

ii) Program Effectiveness

Vitamin D fortification represents an example of a successful fortification program that not only ensures a source of an essential nutrient in the Canadian diet but also protects against excessive intakes. The addition of iodine to salt virtually eliminated endemic goitre associated with soils low in iodine in large areas of Canada. Vitamin C addition to evaporated milk has been responsible for the elimination of infantile scurvy in parts of Canada where evaporated milk continues to be used for infant feeding. Evaporated milk also comprises a significant dietary source of vitamins C and D in certain Northern populations and in Newfoundland.

The addition of vitamins and minerals to foods in Canada is permitted or required for other reasons besides fortification. The restoration of thiamine, riboflavin, niacin and iron to flour and other refined cereal products and vitamin A to fat-reduced milks contribute substantially to the intake of these nutrients. The principle of nutritional equivalence of substitute foods has been applied in setting requirements for products simulating meat, egg and poultry products and most recently in determining levels of addition of nutrients to plant-based beverages, such as soy milks used in place of milk. Regulations controlling the amounts of vitamins and mineral nutrients in formulated foods used as sole sources of nutrition, such as infant formulas, meal replacements and formulated liquid diets, protect the users of those products from nutritional deficiencies/excesses.

iii) Food and Drugs Act and Regulations

As a result of the regulatory provisions promulgated in 1964 (Part D Division 3 of the Food and Drug Regulations), addition of micronutrients to foods in Canada is strictly controlled. The authority for these regulations is the Food and Drugs Act, Sections 4(a) and 5(1)[5]. The Regulations list the foods to which micronutrients may be added and the micronutrients that may be added to these foods (Appendix D). This is an example of a positive listing approach. The Regulations state the amount of nutrient that must be present in the food at the time of purchase. These Regulations apply to all foods sold in Canada, whether imported or domestically produced.

To add to the list of foods that may contain added micronutrients or to the list of nutrients,

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[4] Health Canada, Health Protection Branch, Mandatory Addition of Vitamins A and D to Milk - Background Paper, July 6, 1990 (Available from Nutrition Evaluation Division, Food Directorate, HPB).

[5] Section 4(a) states:
No person shall sell an article of food that (a) has in or upon it any poisonous or harmful substance.
Section 5(1) states:
No person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

an amendment is required to the Food and Drug Regulations. To evaluate petitions for such amendments, the former Food and Drug Directorate of Health and Welfare Canada proposed guidelines published in 1971 in Trade Information Letter No. 351, Proposed Guidelines for the Addition of Nutrients to Foods (Appendix E).

These proposed guidelines were unchallenged and remained the basis for Canadian policy on the addition of nutrients to foods until June 1997, when new regulations were promulgated providing for Interim Marketing Authorizations (IMA) (B.01.056(3)(e)). The IMA regulations provide a way "to allow a food not in compliance with [certain sections of] the Regulations to be marketed while an amendment to permit its on-going legal sale is being processed."[6] This means that foods containing added vitamins, minerals or amino acids for which no provision for such addition exists in the Regulations may be sold if an IMA has been issued. To get the IMA, an evaluation must be done to determine if the addition is in accordance with the Codex principles for the addition of nutrients to foods. This is not significantly different from the approach prior to the IMA regulations. These regulations only serve to reduce the delay in getting to market products that meet proposed changes to the Regulations that have been accepted in principle.

The Codex Alimentarius Commission General Principles for the Addition of Essential Nutrients to Foods, adopted by Codex Alimentarius in 1987[7], are now incorporated by reference into the Food and Drug Regulations with respect to the application of the IMA regulations. These principles state that the purpose of nutrient additions to foods should be as follows:

Restoration

Restoration means addition of essential nutrient(s) lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage and handling. Where the food has been identified as a significant source[8] of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.

Nutritional Equivalence of Substitute Food s

Nutritional equivalence means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion of 100 kcal of the food at a level of 5%

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[6] Health Canada, Schedule No. 923 (Interim Marketing Authorization (IMA)), Regulatory Impact Analysis Statement, Canada Gazette Part II, July 23, 1997.

[7] Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Volume 4, Rome, 1994, pp. 9-12.

[8] A food should be considered a significant source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amount equal to or greater than 10% of the recommended nutrient intake in a reasonable daily intake. (Codex, 1994).

or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts. Where a substitute food is intended to replace a food which has been identified as a significant source[9] of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

Fortification
Fortification means addition of one or more essential nutrients to a food whether or not it is normally contained in the food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

Appropriate Nutrient Composition of Special Purpose Foods
Special purpose foods are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use (Appendix F).

These are very similar to the rationales published in Canada's earlier Trade Information Letter (Appendix E). The Codex Principles go further in that they define terms and provide additional guidance regarding such things as: the need to avoid levels that may lead to adverse effects; considering other sources of the nutrients in determining appropriate levels of addition; the need to ensure that the food is appropriate to act as a vehicle for delivering the nutrient in the case of fortification; the bioavailability of the nutrient in the food; and the technical feasibility of the addition, etc.

iv) Labelling and Claims

Added micronutrients must be declared in the list of ingredients on food labels and the quantity of the added micronutrient in the food must be stated. Exceptions to this are the vitamins and minerals added to certain foods (including margarine, flour and milk) when they are used as ingredients of other foods. The types of claims that are permitted respecting micronutrients on labels and in advertising of foods (and drugs) are strictly controlled under the Food and Drug Regulations. They are restricted to descriptive content claims (e.g. "good source of .. ", "excellent source ..") and to claims regarding generally accepted physiological functions (also known as biological role claims or structure/function claims). Health claims that relate micronutrients to the prevention or treatment of disease are prohibited on labels and in advertising of both drugs and foods. The issue of health claims for foods is currently being reviewed in a separate project.[10]

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[9] A food being substituted or partially substituted should be considered a significant source of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended nutrient intake. (Codex, 1994).

[10] The Joint Food and Therapeutic Products Directorates Project on Functional Foods and Nutraceuticals. (The discussion document and draft policy options analysis paper are available on the Health Canada website: << *http://www.hc-sc.gc.ca/hpb-dgps/therapeut* >> go to Functional Foods & Nutraceuticals).

v) Vitamin and Mineral Nutrient Supplements

Vitamin and mineral supplements are classified as "drugs" rather than foods. This policy is based on the fact that food is the primary source of vitamins and minerals and if supplements are needed, it is considered to be due to an insufficiency of the diet to meet these nutrient needs of the individual. They are therefore, being used to prevent or treat a deficiency disease, and hence fall within the definition of a drug, Section 2 of the Food and Drugs Act.

The regulation of vitamin and mineral supplements along with herbs and botanical products and other natural health products is currently under review by the Parliamentary Standing Committee on Health. This Committee is expected to report during November, 1998.

vi) Sports Nutrition Products

Sports nutrition products include a broad range of products, some of which are foods and some of which are drugs. Examples are sports bars, sports nutritional supplements, fluid replacement drinks, endurance supplements, "fat burners", "weight gainers", and muscle growth products/protein powders. The only food products in this category that may contain added vitamins or minerals are those meeting the definition of nutritional supplements found in the Food and Drug Regulations (Section B.01.001).

Once considered fringe products, sold only to weight lifters, etc., sales of sports nutrition products have grown rapidly and now encompass a broad cross section of the population. They are sold in pharmacies, department stores, supermarkets, health food stores and sports equipment specialty stores.

A large proportion of sports nutrition products sold in the Canadian market are imported, mainly from the United States. Many of the imported products and some domestic products are in violation of the Food and Drug Regulations with respect to vitamin, mineral and amino acid fortification. Many are fortified when no provisions exist for their fortification or at levels well above those stated in the Regulations (eg: vanadyl sulphate, chromium picolinate, vitamin E, zinc and many more).

vii) Herbal and Other Supplements / Natural Health Products

Many herbs, botanicals and other supplements are considered drugs. However, many do not fall within the drug category, either because they do not have claims or they are not sufficiently pharmacologically active, and are regulated as foods. These products are also enjoying considerable sales growth, being marketed to baby boomers and seniors. Although there is no provision for the addition of vitamins and minerals to these foods, they are still frequently added in violation of Part D of the Regulations.

As mentioned above, in October, 1997, the Standing Committee on Health of the House of Commons was asked to review the current regulatory framework for natural health products including traditional herbal medicines, homeopathic preparations and vitamin and mineral supplements. The Committee has heard from many witnesses, including consumers, on issues related to safety, quality and efficacy of these products. The Standing Committee is expected to make

recommendations this fall on changes, if any, which should be made to the legislation, regulations, or regulatory policies currently being used to govern these products.

Health Canada has provided information and clarification to the members of the Standing Committee on Health and researchers during the review period. Descriptions of activities of both the Food Directorate and the Therapeutic Products Programme on related issues such as nutraceuticals/functional foods, food fortification and expanded claims for vitamins and minerals have been provided.

viii) Compliance Programs

Ongoing compliance and food inspection programs are carried out by the Canadian Food Inspection Agency (CFIA) to verify that manufacturers and importers meet the Regulations for the addition of vitamins and minerals to foods and for associated labelling.

The CFIA is adopting new inspection systems based on the principles of sound science and effective risk management. Managing the risks is the collaborative responsibility of the CFIA and its industry and government partners.

At the heart of the new inspection systems are the principles of Hazard Analysis Critical Control Points (HACCP). The key element of an HACCP-based system is the exercising of control throughout the manufacturing process, at critical steps (e.g. adding a vitamin or mineral nutrient) called Critical Control Points (CCPs), before the food is packaged.

In addition to new inspection systems, the CFIA continues to use traditional inspection methodologies directed at finished food products as appropriate.

ix) Canadian Consumer

Canadian consumers are interested in taking personal responsibility for their health and want credible information about health and health issues[11]. Canadians recognize that having a balanced lifestyle, eating nutritious food, exercising, not smoking and immunization are important ingredients in taking control of one's health[11]. Many of today's consumers rely on a variety of sources for health[11] and nutrition[12] information and use alternative health as a complement to traditional health care[11,13]. As the population ages and becomes more culturally and linguistically diverse, and as illiteracy persists, there is a need to provide differing levels of health information in a variety of formats[11]. There may also be an increased need for 'nutrient-dense' foods or those that address the needs of consumers on special diets.

Most (64%) Canadians believe that they are in excellent or very good health, although self-

[11] National Forum on Health. Report on Dialogue with Canadians. July 1996.

[12] National Institute of Nutrition. Tracking Nutrition Trends: 1989-1994-1997. Ottawa, ON, 1997.

[13] Federal, Provincial and Territorial Advisory Committee on Population Health. Report on the Health of Canadians: Technical Appendix. Ottawa, ON, 1996.

perceived health status declines as age increases[13].

Nutrition continues to be important to most Canadians in choosing the foods they eat, especially among women. When asked what they are doing to eat well, Canadians report eating more vegetables and fruit, choosing lower fat products, following *Canada's Food Guide to Healthy Eating* and cutting back on sweets and 'junk' food. Canadian consumers continue to use product labels as a source of nutrition information, although difficulty in understanding them is expressed by some (23%). Other popular sources of nutrition information include nutrition information from electronic and print media, family, relatives and colleagues. In many cases this information is at the level of a hypothesis and there may be little validated scientific evidence to support it. Food and nutrition concerns expressed by a majority (67%) of Canadian consumers include vitamins, calcium, food poisoning, chemical residues in or on food, fat, saturated fats and fibre[12].

II) Safety

One of the General Principles outlined by Codex for the addition of essential nutrients to foods is "to prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances". Although nutrients are required for health, anything taken in excess can be toxic. In the nutritional context, Bertrand pointed out almost a century ago that essential nutrients present two risks: one of deficiency and another of toxicity[14].

Considerations of safety go beyond acknowledgment of direct or acute adverse effects associated with over-consumption of a nutrient. More subtle impacts result from interactions or imbalances between nutrients, or between nutrients and drugs. These may act to change the bioavailability or efficacy of the nutrients or drugs. The resultant alterations in metabolism or physiology may have important public health relevance.

When altering the food supply, consideration must be given to long-term effects. Long-term chronic effects are defined in classical toxicology as representing the results of exposure over a significant proportion of an individual's lifetime. Chronic adverse effects will potentially include influences on slowly-developing diseases such as heart disease or cancer, as well as possible developmental or reproductive disturbances or effects on behaviour, intellectual or other neurological functions.

There can be differences in nutritional needs and/or tolerances between population subgroups, due to factors such as age, activity level, differences in health status, genetic predisposition or the presence of preexisting chronic disease. Demographic differences in exposure levels to fortified nutrients may also be relevant. For example, in the effort to provide additional levels of some nutrient(s) to groups who may consume a low quantity of food, it should be remembered that some groups, such as adolescent males, may eat many foods in large quantities.

It must be recognized that currently available scientific data may be inadequate to fully

[14] Bertrand, G (1912) in *8th International Congress of Applied Chemistry*, vol. 28, New York, pp 30-49.

evaluate the potential for adverse effects from over-ingestion of micronutrients. Organizations such as the Food and Nutrition Board of the US National Academy of Sciences, WHO/FAO and the European Union are just beginning to deal with this issue. Lack of complete information must not present a barrier to reasonable addition of micronutrients to foods. Careful consideration will be critical to the formulation of policies that can protect the interests of all into the next century.

III) Dietary Reference Intakes (DRIs)

The Food and Nutrition Board of the US National Academy of Sciences is in the process of developing Dietary Reference Intakes (DRIs) for nutrients (Appendix G). These are reference values that may be used for planning and assessing diets for healthy populations and for many other purposes including judging the need for public health interventions such as food fortification and formulating foods. Canadian scientists are participating in the review which is being supported in part by Health Canada. The reviews are being carried out sequentially as funding becomes available, and reports will be released at intervals over the next 4 years. The DRIs will ultimately replace the Recommended Nutrient Intakes in Canada and the Recommended Dietary Allowances in the United States.

The DRIs encompass the Estimated Average Requirement (EAR), the Recommended Dietary Allowance (RDA), the Adequate Intake (AI) and the Tolerable Upper Intake Level (UL). The first three values are defined by indicators of nutrient adequacy which may extend to reduction in risk of chronic disease or disorders where evidence is available; the fourth by indicators of excess where available. The DRIs are of relevance to the implementation of policies on the addition of nutrients to foods (Appendix H).

IV) International

i) Practices in Other Countries

The regulations governing addition of vitamins and mineral nutrients to foods vary widely from country to country. They range from free nutrient addition with only basic requirements for safety and labelling that does not mislead the consumer (e.g. Austria) to very limited addition controlled by the authorities (e.g. Italy). The regulatory possibilities include notification requirements and general permissions[15]. A table summarizing the regulations/practices in other countries is provided in Appendix I.

The 161 member countries of the Codex Alimentarius Commission are encouraged to adopt the Codex Standards and related texts. The fact that these texts are now used as a reference by the World Trade Organization in trade disputes provides further incentive for members to base national requirements on their provisions.

ii) Trade Considerations

[15] Nordic Council of Ministers, Addition of Nutrients to Foods - Principles and Practices, Copenhagen, TemaNord 1995:643.

Canada is a signatory to several bilateral and multilateral trade agreements, including the North American Free Trade Agreement and the Uruguay Round of Multilateral Trade Negotiations under the General Agreement of Tariffs and Trade 1994, leading to the World Trade Organization. These agreements recognize that consumer protection and health and safety measures are legitimate national objectives. A country may establish a level of protection for human health that it considers appropriate. To achieve this level, countries may adopt measures provided they are based on an appropriate risk assessment and they are not applied in an arbitrary or discriminatory manner. A brief summary of Canada's obligations under international trade agreements can be found in Appendix J.

D. Alternatives to Food Fortification

If there is evidence indicating that the Canadian diet is not meeting the nutrient needs of Canadians, is the addition of vitamins and minerals to foods the only alternative? There are a variety of approaches, each with their own advantages and disadvantages, which can be used to achieve optimal health through nutrition. One option is to change the food supply by the addition of vitamins and minerals to specific foods or to a range of products. Inherent in this approach are questions surrounding how to target the fortification to those who need the intervention while avoiding potential adverse effects, such as excessive or imbalanced intakes. Other questions involve the choice of mandatory or voluntary programs, the latter of which require education for their effective implementation. A second option is education. Can we create easily understandable messages that will influence dietary behaviours and improve the intake of nutrients of concern? A third option is the use of supplements. Supplements may be the best approach when specific sub-populations have a clear and distinct need, but may involve additional health-care costs. This approach is clearly the one most easily utilized on an individual basis, but has rarely been used as a population intervention approach; its implementation would also require a large education component. Ultimately, some combination of all these approaches may be an effective strategy to address any gaps that may exist between what we need and what we consume.

5. GUIDING PRINCIPLES

A set of guiding principles was presented to stakeholders at the March Consultation Workshop. Participants were asked to comment on the appropriateness and completeness of the Guiding Principles, report on what they liked, identify their concerns, and suggest improvements. Full details concerning the comments on the draft guiding principles and suggestions for improvement are contained in the Synopsis Report of the March 27, 1998 Stakeholder Consultation Workshop to Issue Identification[16].

The EAP and WG reviewed the comments on the guiding principles during their June and September meetings. Several changes were made so that the resultant Guiding Principles would be in line with the suggestions made at the March Consultation Workshop.

Guiding Principles for the Policy Review Concerning the Addition of Vitamins and Minerals to Foods

1. The policy must ensure that the addition of vitamins and minerals to foods maintains and improves the nutritional quality of the food supply, consistent with public health priorities, goals and education programs and aims to protect and enhance the health of the population including subgroups at identified risk.

2. The policy must ensure that the addition of vitamins and minerals to foods does not result in health hazards due to nutrient excess, deficits or imbalances. The policy should differentiate nutritional from pharmacological effects.

3. The policy must ensure that decisions are based on the best available evidence.

4. The policy must help to prevent practices which may mislead, deceive or confuse the consumer, and yet facilitate consumer choice.

5. The policy must be flexible enough to respond to the varied and changing demographics and food habits of the Canadian population, and reflect Canadian cultural and social values.

6. The policy must be practical, feasible, effective, enforceable and sensitive to trade and competitiveness issues.

Note: Principles are in order of priority although they are intertwined.

[16] Health Canada, HPB. March 27, 1998 Stakeholder Consultation on Issue Identification, Synopsis of Plenary Sessions. (Available from the Nutrition Evaluation Division, HPB or on the Health Canada website: <<www.hc-sc.gc.ca/datahpb/datafood>> go to Nutritional Sciences/Regulation of Nutritional Quality of Food/Review of HC Policies Concerning the Addition of Vitamins and Minerals to Foods)

6. OBJECTIVES AND OUTCOMES

The Guiding Principles were restated as objectives and outcomes:

Objectives of Food Fortification Policies

1. To maintain and improve health
2. To contribute to a safe and nutritious food supply
3. To contribute to consumer protection from misleading practices and to facilitate consumer choice
4. To facilitate trade and not impede industry competitiveness
5. To incorporate monitoring, review, and evaluation (of policies, regulations and outcomes)

Outcomes of Food Fortification Policies

Policies for the Addition of Vitamins and Minerals to Foods should result in regulations/ guidelines/ standards:

1. that are in line with population health goals
2. that meet (accepted) criteria for risk management
3. that can be met by industry
4. that are relevant and appropriate for consumers
5. that are consistent with international obligations
6. that are effective
7. that are sensitive to trade and competitiveness issues

7. SUMMARY OF ISSUES USED TO DEVELOP CRITERIA

The March 27, 1998 Consultation Workshop on Issue Identification brought together a broad cross-section of stakeholders to identify issues of concern related to this policy initiative. The issues fell within diverse areas such as public health, safety, consumer choice and availability and trade and competitiveness. In order to develop criteria by which to evaluate potential approaches to food fortification, the EAP and WG were asked to review and evaluate the March comments and to identify considerations which would be key to include when developing the policy. The following are the explanatory paragraphs for each theme area followed by a summary of the comments raised at the Workshop and the evaluation done by the EAP and WG at their June and September meetings.

Population Health

Vitamin and mineral addition to foods can be used to maintain and improve the nutritional quality of foods, and thereby protect and enhance the health of Canadians. Policies should be consistent with national nutrition standards and guidance, and public health initiatives. Policies on vitamin and mineral addition to foods should take into account population variability and changing demographics, as well as the continuum from simple nutrient deficiencies to diet-related chronic diseases.

- The total diet principle (Appendix K) needs to be elaborated more fully in order to ensure that we do not lose that message. "There is no magic bullet". Fortification, as an example, needs to be considered in the context of total diet, and diet and education cannot be separated.
- Recognition of vulnerable populations within the national population - question of equity in the population.
- It is also recognized that there is a very difficult balance to be addressed between population variability, consumer demand and safety. Other variables such as cultural diversity and geographical distribution need to be picked up as well.
- The notion of flexibility must also be emphasized.
- Accountabilities must be defined with long term measurable outcomes and a provision for monitoring.
- Should public health needs over-ride individual responsibility for choice, or can these co-exist?
- Disease prevention (acute and chronic) and risk reduction; performance enhancement (cognitive, emotive, reproductive work); improved quality of life (disability-free years, years of independence).
- Adequate nutrient intakes in line with national standards and guidance.

Safety and Effectiveness of Vitamin and Mineral Addition to Foods

Safety:

The addition of vitamins and minerals to foods should not result in increased risk of health hazards due to essential nutrient excesses, deficits or imbalances. Various nutrients are associated with different adverse effects, both in the severity of the effect and in the margin

of safety between requirement and the level at which adverse effects are observed. For some nutrients, little is known about safety. Vitamins and minerals can also impact on the bioavailability and efficacy of other nutrients.

- Risk and benefit - The question of how to assess / balance the risks and benefits needs to be addressed, but there is a clear message to err on the side of caution.
- Concept of upper limit as well as interaction between nutrients; determine what to do with those nutrients for which no upper limit has been set - uncertainty about upper limits; severity of the consequences of exceeding upper limits (Appendix L).
- Margin of safety will be a key consideration when balancing benefits / effectiveness.
- To evaluate the effectiveness or safety, need an estimate of exposure dose. The required precision of that estimate will depend on the margin of safety of the nutrient.
- Decisions must be evidence based. However, there is also a recognition that there are limitations to current science, which is creating a circumstance where we are sometimes working with unverified assumptions; use the best science available.
- Nutrients with unknown RDA or for which an RDA has not been established are outside this policy and should not be added.
- There was an expressed need for the development of a decision making model. A model incorporating safety and effectiveness considerations was suggested; two continua are operating at same time; Both need to be assessed.

  Low risk → High risk

  No health benefit → Benefit
- In order to improve our decision-making capability in the longer term, research into the health outcomes associated with the addition of vitamins and minerals to foods must be conducted along with a review of international experience.
- Need appropriate data on consumption patterns and supplement intake in order to understand potential impacts of fortification.
- There is a need to integrate an appropriate education program.
- Government liability.
- There is a need to differentiate between risk and safety and to understand the principles of risk management (Appendix M).

Effectiveness:

Effectiveness of vitamin and mineral addition to foods can include considerations of a technical nature such as stability, bioavailability, colour, taste, etc., and a consideration of issues surrounding appropriate targeting of the addition to population groups with identified needs while avoiding excessive intakes by other groups.

- Need clearer definition of intended health outcomes; consideration for not including health hazards.
- Need research and monitoring of consumer behaviour and nutritional intake in order to be able to assess effectiveness.
- Vitamins and minerals can impact on the bioavailability of other nutrients.
- Integration of education with implementation and other messaging

Availability and Choice

Adequate choice in the food supply is needed to support healthy eating practices among a broad range of consumers, given cultural, social, economic, demographic and health diversity of the Canadian population. Consumers are looking for increased availability of food choices, including fortified food products.

- Impact on risk management - as it relates to choice; increasing choice and demand for more freedom of choice may lead to a push for acceptance of higher levels of risk which will need to be managed.
- Cost - accessibility issue; an increase in cost may result in some segments of the population losing access to those nutrients which they need; may also have a detrimental or positive effect on industry and jobs; may result in job losses if it becomes less expensive to produce elsewhere.
- Availability is also relative to where you live - rural vs urban issue (should not exacerbate the situation).
- There is a range of individual needs depending on individual circumstances - increase choice / give people what they want but balance with the needs of the sub-population whose choices may be limited now; must provide some benefit to sub-populations at risk.
- Criteria for deciding what additions should be mandatory vs voluntary vs prohibited.
- Education and messaging becomes vital - there must be clarity for consumers and manufacturers to make informed choices based on the associated benefits and risks.
- Consumers want choice; health benefits are seen as the priority while ensuring a balance with freedom of choice.
- Consumer education and information dissemination - these components are necessary.

Trade and Competitiveness

Canada is working toward improving international market access for Canadian food products. Some economists tell us that increased trade will benefit Canada's economy through increasing industry growth, creating jobs and providing choices for consumers.

Canada is a signatory to several bilateral and multilateral agreements, including the North American Free Trade Agreement and the Uruguay Round of Multilateral Trade Negotiations under the General Agreement of Tariffs and Trade 1994, leading to the World Trade Organization. These agreements recognize that consumer protection and health and safety measures are legitimate national objectives. A country may establish a level of protection for human health that it considers appropriate. To achieve this level, countries may adopt measures provided they are based on an appropriate risk assessment and they are not applied in an arbitrary or discriminatory manner.

- Need for flexibility - freedom to innovate leads to growth and competitiveness and provides new products and greater choice to consumers. Current Canadian regime is very restrictive. Canada must become less restrictive with respect to imports, because it exists within a world trade environment.
- Must meet our obligations under various trade agreements (Appendix J).

- North American harmonization - North America is a major market. If we wish to have access to that market, we must be prepared to level the playing field. However, prior to taking action, we must do the appropriate economic analysis.
- Economic Analysis - We must develop an "economic risk assessment" model to look at the pros and cons of harmonization. The model must take into account the risks and benefits on a sector by sector basis and consider levels of potential impacts, including impacts on jobs, the security of the food supply, longer term impacts on domestic producers and processors, etc.
- If health risk is low there doesn't have to be a positive health benefit in order to allow fortification (i.e. consider the economic benefit).
- A great deal of discussion was held around economic benefits/costs of liberalized food fortification policies, the assumptions that would have to be made in order to conduct an economic analysis and the difficulties in reaching industry or sector-wide conclusions.
- Health, Safety and Effectiveness - Need to balance the trade and competitiveness issues and trade opportunities that may exist with population health, safety and effectiveness when developing policy. Must consider cost to industry for public health benefits. Message is that trade should not be the over-riding issue.

8. CRITERIA TO BE USED TO ASSESS POTENTIAL FOOD FORTIFICATION APPROACHES

The issues summarized in the previous section were used to develop criteria by which food fortification policy options could be assessed. The EAP and WG reviewed the issues raised, considered the key elements and then developed criteria which are specific, measurable, achievable, results-based and time-based. The set of criteria developed were defined as either ***screen criteria*** (i.e. if the fortification approach did not pass all the screen criteria, it would not be assessed further), or ***managing/control criteria***. Screen criteria are mandatory, measurable and realistic. Managing/control criteria are more subjective and often less measurable. They represent desirable outcomes or characteristics, and will help to determine the desirable level of control for the proposed fortification approaches.

Criteria to be Used in Assessing Potential Food Fortification Approaches

Screen Criteria

1. Must aim to help all Canadians achieve the recommended intakes (as developed in the DRI process) in line with the principles of a total diet.

2. Must be based on a risk management approach grounded in current science which takes into consideration:
   - recognized Upper Limits
   - nutrient interaction(s)
   - current consumption patterns in the context of total exposure

Managing/Control Criteria

1. Permits a wider distribution of vitamins and minerals in the food supply to enhance consumer choice and availability.

2. Should encompass the principles of Codex and the DRIs.

3. Ensures that trade agreement obligations are met.

4. Allows the addition of a nutrient to a food, where the addition has no defined health benefit but poses little risk, so as not to impede trade and competitiveness.

5. Prevents practices which may mislead or deceive the consumer, and yet facilitates consumer choice.

Points of Clarification Regarding the Criteria

The EAP and WG clarified certain issues/points regarding several criteria to ensure that the intent was clearly understood.

- Clarification of our intent as it relates to the DRI process (clarify "help achieve the recommended intakes"):
  - Aims to help all Canadians achieve the recommended intakes. This includes vulnerable population subgroups.
  - Intent is to ensure that the evidence for the role of nutrients in reducing risk of disease and developmental disorders (optimal health) is considered and not just the evidence for the traditional role of nutrients related to deficiency diseases.
  - Intent is to ensure that the upper limits are not exceeded.
  - There was no agreement on whether this criterion would be used to eliminate approaches that provided more than the recommended intakes.

- Clarification as to what we think it takes to adhere to the principles of a total diet.
  - The concepts of total diet and total exposure were clarified (Appendix K).
  - Approach should not encourage the consumer to consume 100% of the RDA through one food. We don't want to discourage choosing a variety of foods to meet total dietary needs.

- What if you do not have data? (eg: upper limits have not been established for some nutrients; may not have complete data on nutrient interaction; may not have complete consumption data)
  - It was clarified that a risk management approach (Appendix M) considers all these aspects and uses the best available evidence. Screen criterion #2 has to assume that a risk management assessment could be done, not that it has been done.

- The concept of "encompass the principles of Codex and the DRIs" should be defined.
  - Intent of this criterion is to ensure that the principles of Codex are adhered to, without being restricted to correcting deficiencies, thus allowing food fortification to be used to meet DRIs.

9. FOOD FORTIFICATION APPROACHES FOR EVALUATION

A series of food fortification approaches which describe reasons for adding vitamins and minerals to foods was developed by the EAP and WG. This series of food fortification approaches covers the full range of possible reasons for adding vitamins and minerals to foods from the most restrictive to the free addition of vitamins and minerals to foods. They are ordered in a way that would result in a progressive expansion of addition of vitamins and minerals to foods with a concomitant reduction in government involvement. It is envisioned that the final Canadian policy for the addition of vitamins and minerals to foods will incorporate a number of these approaches.

Food Fortification Approaches for Evaluation

1. Maintain nutritional quality of foods through; a) restoration; b) nutritional equivalence of substitute foods.

2. Retain mandatory food fortification programs to prevent deficiencies.

3. Expand fortification programs to improve the nutritional quality of the food supply: Public health approach to meet DRIs → recognize optimal health approach (ie: situations where new "nutritional recommendations" are increased and are not being met through current dietary practices).

4. Fortification of special purpose foods targeted to a specific population group or market.

5. Fortification programs to enable foods to be equivalent to moderate vitamin and mineral supplements (ie: allow fortification beyond demonstrated/proven public health needs). Eg: fortification between ~60 - 100% of RDA per serving.

6. Addition of vitamins and minerals beyond clear health benefit but within safety range. Eg: > 100% of RDA per serving but < Upper Limits per day.

7. Free addition of vitamins and minerals as food ingredients as long as no health hazards exist and labelling does not mislead or deceive.
   With implementation options:
   - A) positive list of low risk nutrients
   - B) negative list of non-permitted nutrients, or
   - C) no list - only control after problems arise

10. ANALYSIS OF FOOD FORTIFICATION APPROACHES

The food fortification approaches for evaluation are listed below with a brief explanation of the intent of the approach and examples to aid in their understanding. The EAP and WG analysed and evaluated these food fortification approaches using the agreed-upon criteria and keeping in mind the regulatory and implementation implications. Pros and cons, as well as comments, were recorded for the new approaches and are recorded here to facilitate discussions and highlight the many issues which were considered.

1. Maintain nutritional quality of foods through; a) restoration; b) nutritional equivalence of substitute foods.

Explanation/Intent:

The intent and principles surrounding restoration and nutritional equivalence of substitute foods have been explained earlier in this document (see page 6).

Examples: (See Appendix D for full details)

Examples of restoration programs in Canada include:

- vitamin A added to all fat-reduced cow's milk (partially skimmed, skim)
- thiamine, riboflavin, niacin and iron added to white flour

Examples of fortification for nutritional equivalence of substitute foods in Canada include:

- vitamins and minerals added to infant formulas
- vitamins and minerals added to simulated meat products and products simulating whole egg
- vitamin A added to margarine and other similar substitutes for butter

EAP/WG Summary of Approach 1

Unanimous agreement that restoration and nutritional equivalence of substitute foods are valid reasons for the addition of vitamins and minerals to foods. The group did not evaluate the pros and cons of this approach.

2. Retain mandatory food fortification programs to prevent deficiencies.

Explanation/Intent:

The intent and principles surrounding this approach have been stated by Codex[17] as follows:

> 6.2.1. There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.
>
> 6.2.2. The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.
>
> 6.2.3. The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.
>
> 6.2.4. The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk.
>
> 6.2.5. The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

Examples: (See Appendix D for full details)

Examples of mandatory food fortification in the Canadian food supply are:

- vitamin D in all cow`s milk (fluid, powdered, concentrated or evaporated)

  There are few sources of vitamin D in the Canadian diet and exposure to sunlight cannot be relied upon to supply sufficient vitamin D. Rickets due to vitamin D deficiency in children practically disappeared when mandatory vitamin D-fortified fluid milk became universally available. Details surrounding vitamin D fortification have been discussed earlier in this document (see page 4).

- iodine in table salt

  Large areas of Canada have soils low in iodine; endemic goitre has been virtually eliminated through the mandatory addition of iodine to table salt.

EAP/WG Summary of Approach 2

Unanimous agreement that this is a valid reason for the addition of vitamins and minerals to foods. The group did not evaluate the pros and cons of this approach.

[17] Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission, Volume 4, Rome, 1994, p. 12.

3. Expand fortification program to improve nutritional quality of food supply: Public health approach to meet DRIs → recognize optimal health approach (ie: situations where new "nutritional recommendations" are increased and not being met through current dietary practices).

Explanation/Intent:

This is a new approach which was added to ensure that the current definition of DRIs (Appendix H) would be considered as one of the potential reasons for the addition of vitamins and minerals to foods, i.e. the evidence for the role of nutrients in reducing the risk of disease and developmental disorders (optimal health) is considered and not just the evidence for the traditional role of nutrients related to deficiency diseases. Evidence concerning the use of nutrients in the treatment, mitigation or cure of a disease or disability is not considered part of the current DRIs and therefore is not part of this potential approach.

EAP and WG evaluation:

Pros	*Cons*
• Meet DRIs for general population or sub-group. • Help trade and competitiveness (if DRI levels are harmonized) • Increase nutrient density of food supply • Greater choice - fortified and non-fortified foods • More fortified foods at lower levels • Well defined process used to establish DRIs • Adds flexibility • Important concept to get out - dynamic system	• Implementation of approach might be complex (high risk nutrients - need dietary monitoring) • Resource intensive - expensive inputs (data on food consumption) or else assumptions need to be made.

Control/Implementation Issues:

- Positive list for certain nutrients?
- Voluntary or mandatory?
- May need to consider the addition of sets of nutrients or co-fortificants.
- In the case of some nutrients, modelling to identify targets; for others, harmonization; wide variety of approaches are possible depending on nutrients and risk profile.
- Targeted foods through modelling and by class of foods.
- Nutrient and amount are key in this approach as opposed to food being the control point.
- Claims are more of an issue here than in approaches 1 and 2.

EAP/WG Summary of Approach 3

Unanimous agreement that this is an appropriate reason for adding vitamins and minerals to foods.

4. Fortification of special purpose foods targeted to a specific population group or market.

Explanation/Intent:

This approach is part of Health Canada's current policies on food fortification. The EAP and WG however, view an expanded role for this approach which could include a wider variety of products than currently permitted (eg: fortified soups or frozen dinners targeted to seniors or others).

Examples: (Full details in Appendix D)

Examples of special purpose foods with added nutrients currently permitted and sold in Canada include:

- meal replacements and nutritional supplements
- infant cereals

EAP and WG evaluation:

Pros	*Cons*
• Improve nutrient intake of population at risk • Efficient delivery • Enhance consumer choice (real food vs food in a can) • Greater flexibility in product development. • Possibly more popular with consumers • Wider application than just elderly (AIDS, anorexia, children) • Would increase nutrient density of foods to enhance nutrition in target groups	• Increased cost therefore not available to all in target group • Need for control in targeting • Must ensure that foods reach target group without risking non-target groups.

EAP/WG Summary of Approach 4

Unanimous agreement that this is an appropriate reason for adding vitamins and minerals to foods.

5. Fortification programs to enable foods to be equivalent to moderate vitamin and mineral supplements (ie: allow fortification beyond demonstrated/proven public health needs). Eg: fortification between ~60 - 100% of RDA per serving .

Explanation/Intent:

This approach deals with whether or not foods should be viewed as an appropriate delivery vehicle for vitamin and mineral supplements. This approach would provide the consumer with the option of consuming a vitamin and mineral supplement in a food form rather than a pill form. This approach is currently not permitted in Canada or under Codex General Principles. There are several examples of food products (some cereals and beverages) marketed and sold as nutritional supplements in the US.

EAP and WG evaluation:

Pros	*Cons*
• Might catch some sub-groups not targeted • Will provide a level playing field with drugs	• Risk of people consuming multiple servings per day • May permit supplements which are not nutritionally well formulated • Changing use / purpose of food - potential for abuse • Undermines total diet approach • Questionable public health implications • No indication of need in population

6. Addition of vitamins and minerals beyond clear health benefit but within safety range. Eg: > 100% of RDA per serving but < Upper Limits per day .

Explanation/Intent:

This is a further expansion of Approach #5. In this approach foods would be treated in a similar fashion as vitamin and mineral supplements, which may contain more than 100% of the RDA.

EAP and WG evaluation:

Pros	*Cons*
• Provide competition to supplement industry • Ensure against deficiencies • Some products in US and elsewhere would fall under category and vice versa • Extend consumer choice • Positive impact on industry • Easy to regulate • Could promote food for therapeutic use • More attractive to consumers	• Undermines total diet • More complicated education approach • Cautionary labelling may be needed • Possible negative nutrient interactions • Multiple servings could result in safety issue • Chronic consumption could result in safety issue • More difficult to limit access to children • More complicated food selection • Impact on some industries • More complicated monitoring • Potential for too high consumption of nutrients • Impact on supplement usage or choice • Creates "more is better" concept (could be controlled with labelling?)

Fundamental Issues underlying Approaches 5 & 6:

- Should foods under options 5 and 6 be called therapeutic foods?
- If we endorse these approaches, we are going beyond general foods and moving into a different category which speaks to vitamin and mineral supplements delivered via a food vehicle. Is this acceptable? There was a low degree of comfort overall in the group with these approaches.

EAP/WG Summary for Approaches 5 & 6

The majority did not agree that approaches 5 and 6 were appropriate reasons for adding vitamins and minerals to foods; not unanimous.

7. Free addition of vitamins and minerals as food ingredients as long as no health hazards exist and labelling does not mislead or deceive.
With implementation options:

A) positive list of low risk nutrients
B) negative list of non-permitted nutrients, or
C) no list - only control after problems arise

Explanation/Intent:

This approach was included so that a full range of possible approaches for dealing with the addition of vitamins and minerals to foods would be evaluated. This represents an option which focuses primarily on safety with no attention given to the public health role for the addition of vitamins and minerals to foods. This approach would mean that:

- there are no criteria for demonstrating health benefits
- there are no restrictions on which foods can be fortified
- there may be prescribed maximum limits

EAP and WG evaluation: (see following page)

EAP/WG Summary of Approach 7

Unanimous agreement that this is **not** an appropriate reason or approach for controlling the addition of vitamins and minerals to foods.

EAP and WG evaluation:
The following table reports the evaluation of the three implementation options of this approach

Pros	*A*	*B*	*C*	*Cons*	*A*	*B*	*C*
• Fast response for industry to get product to market	✓	✓	✓	• Big onus on Government to establish what's safe	✓	✓	✓
• Ease of market introduction	✓	✓	✓	• Hard for industry to define what's permitted	✓	✓	✓
• Increased consumer choice	✓	✓	✓	• Possible increase incidences of confusion and people being misled	✓	✓	✓
• Reduce trade barriers	✓	✓	✓	• High education requirement for consumers	✓	✓	✓
• Simple for industry to apply	✓	✓	✓	• Unknown risk of chronic high consumption, acute toxicity and competitive absorption of nutrients	✓	✓	✓
• Increases Canadian competitiveness for US market and internationally	✓	✓	✓	• How to pinpoint cause of problems (ie which single nutrient?)	✓	✓	✓
• Flexibility in product development	✓	✓	✓	• Food composition data bases more complex	✓	✓	✓
• Increase the probability of individual with low intake of low risk nutrients meeting the RDA for that nutrient	✓	✓	✓	• Consumers may become blasé about healthy eating	✓	✓	✓
• Low government involvement in regulation	✓	✓	✓	• Undermines total diet approach	✓	✓	✓
				• Trivializes other nutrients, risk of decreased intake of nutrients not on the list (those with no market potential)	✓	✓	✓
				• Could cause a shift in consumption away from unprocessed food (could increase sodium and decrease potassium, fibre & other beneficial non-nutrients)	✓	✓	✓
				• Need monitoring system	✓	✓	✓
				• Speed to rectify problems - would be slow	✓	✓	✓
				• Speed to alter the list - would be slow	✓	✓	✓
				• More liability on Government	✓	✓	✓
				• Risk Management is difficult	✓	✓	✓
				• Major government involvement in enforcement			✓
				• More litigation may result			✓
				• More liability for industry			✓

11. OTHER CONSIDERATIONS

Two additional issues were originally described as potential food fortification approaches which were evaluated by the External Advisory Panel and Government Working Group at their joint meetings held in June and September 1998. At these meetings, it became apparent that the issues surrounding (1) the selection of appropriate food vehicles, and (2) the consideration of trade and competitiveness concerns were more appropriately discussed as other considerations in our discussion of agreed upon approaches rather than standing as approaches in and of themselves. Should these considerations then be applied to all approaches?

1. Food Vehicle:

I. ***Should foods of low nutrient density which do not otherwise fit into a food group be considered as a vehicle for food fortification?*** (Eg: confections, snacks, soft drinks, chips/savoury snacks, condiments, jam/jellies).

The pros and cons surrounding this question were as follows:

Pros	*Cons*
• Widely consumed especially by the poor • Major source of energy • Reaches an at-risk population (assuming same cost) • Helps "fun food" industry • Increase nutrient density of foods • Consumed by population on the run • Easier to choose foods - more equitable treatment of all foods	• Potential to increase intake of "fun foods" • Confuse population which is trying to "eat healthy" • Displacement of other constituents in the food matrix (beyond the known essential vitamins and minerals) • Negatively impacts the credibility of nutrition education; fortification of these foods should not be encouraged; goes against the principles and guidelines for healthy eating, ie Canada's Food Guide to Healthy Eating • Other nutrients will be omitted - might lead to other nutrient deficiencies • Exposure to more food additives • Instill lack of confidence in nutritional values of food supply

EAP/WG Recommendation

No pressing public health need or consumer demand to fortify confectionary products, but would be willing to consider these vehicles in very specific circumstances. Issues of control must be considered.

II. ***Should the intended use of the food(s) be considered rather than its inherent nutritional quality?*** There are situations in which foods with little inherent nutritional quality are currently fortified (eg: fruit drinks (sugar, flavour), highly pre-sweetened breakfast cereals). Is it considered appropriate to fortify these types of products because of the way they are used in the diet?

EAP/WG Recommendation

The group agreed that the intended use of the food(s) should be the main consideration when evaluating the food vehicle.

III. ***Should commodity foods be considered as a potential vehicle for the addition of vitamins and minerals to foods?*** Commodity foods are unformulated foods sold as produced by agriculture, but does not mean unprocessed, as some agricultural products are processed, for example, milk is pasteurized, but is currently viewed as a commodity food.

EAP/WG Recommendation

Commodity foods should be included in the discussions as potential food vehicles for fortification.

B. Harmonization and Trade

I. ***Should the addition of vitamins and minerals to foods be allowed for reasons of harmonization and trade considerations when safety issues are not of concern and there is no nutritional need? If so, what limits should be placed on food fortification when making allowances for trade?*** For example, should the policy incorporate a statement such as: Where the proposed level of addition of one or more vitamin(s) or mineral(s) is different from those currently permitted in Canada, but is consistent with one of the agreed upon approaches for food fortification in Canada, provided that the addition is not associated with safety concerns or adverse health effects, should these levels be accepted? Should this determination be done on a case-by-case approach?

During the EAP and WG's deliberations concerning this issue, the following statements were written to describe what was being considered:

- Need to use wording which highlights facilitation of trade and downplays using fortification for marketing.

- No requirement for demonstrable health benefit; no nutritional justification
- Must be no safety concerns.
- Enables trade of products available elsewhere.
- Need a clear delineation of parameters to avoid a "free-for-all" and an undoing of all of our criteria and approaches.

What needs or concerns we were trying to address by this approach:

- Addressing primarily trade and competitiveness. Concern - ability to manufacture a product suitable for distribution in Canada and other trading markets.
- Addresses the concerns with non-complying imports.
- Consumer perceived needs.
- Advances Canada as a world player in terms of innovation (not unique to this approach - processes, manufacturing, confidence, etc.).
- Provides for growth in the value-added sector.

Two examples can be used to illustrate this point:

(A) **No nutritional need** :

No adverse effects have been associated with excess intakes of ***riboflavin*** from food or supplements, although the potential for adverse effects has not been systematically evaluated. No UL has been set for riboflavin by the FNB of the NAS[18]. Health Canada currently does not permit the addition of riboflavin to cereals because the amount of riboflavin naturally present in a 30 g serving of a whole grain cereal is not a nutritionally significant amount when considering restoration of nutrients (see p.6). In addition, there is no evidence to suggest that Canadians are not already receiving adequate riboflavin. Intakes in the Quebec provincial survey were 1.3 - 1.7 and 1.8 - 2.5 mg/d for females and males respectively. The 1990 Canadian RNI was 1.0-1.4 mg/d and the new 1998 RDAs are set at 1.1 and 1.3 mg/d for females and males respectively. In the US, breakfast cereals are commonly fortified to a level of 25-35% of the US Reference Daily Intakes for many of the B vitamins. The sole reason to permit riboflavin addition to cereals in Canada would be to facilitate trade with the US.

(B) **Proposed level exceeds that currently permitted in Canada (under restoration)** :

In the 1998 DRI report on B vitamins[18], no reports of adverse effects of oral ***pantothenic acid*** were found, nor were any subgroups susceptible to adverse effects of excess pantothenic acid identified. According to this report, since no adverse effects have been associated with high intakes of pantothenic acid, the risk due to exposure is most likely low. No UL was established for pantothenic acid. In Canada, we permit the addition of pantothenic acid to cereals under the conditions for restoration and it is typically found at approximately 7% of the RDI of 7 mg (i.e. a breakfast cereal would provide 0.5 mg per serving). Pantothenic acid intakes in the Quebec provincial survey were 4-6 mg/d. The

[18] Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline. (Prepublication Copy). Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, 1998.

1990 Canadian RNI committee did not establish an RNI for pantothenic acid, although they considered that intakes were adequate. The new 1998 AI for pantothenic acid are set at 5 mg/d for both males and females. Breakfast cereals in the US are commonly fortified to a level of 25-35% of the US Reference Daily Intake, which for pantothenic acid is 10 mg. The US Reference Daily Intakes are based on the 1968 RDA for pantothenic acid which has subsequently been halved. Harmonization of the level of pantothenic acid with that permissible in the US, would result in a serving providing 2.5 to 3.5 mg of pantothenic acid, or 50 to 70% of the new AIs, although without concerns for safety.

The pros and cons surrounding this question were as follows:

Pros	*Cons*
• Enables trade of products available elsewhere • Facilitates trade; reduces barriers to trade • Advances Canada as a world player in terms of innovation (not unique to this approach - processes, manufacturing, confidence, etc.) • Provides for growth in the value-added sector; provides for more opportunities to add value to products • Increases choice for consumers	• Need a clear delineation of parameters to avoid a "free-for-all" and an undoing of all of our criteria and approaches. • How to decide when it's OK to harmonize and when it isn't • May as well just change our regulations • May be constantly making adjustments based on capricious, unregulated changes in other countries.

EAP/WG Recommendation

Insufficient time was spent to allow a full evaluation of this question.

12. IMPLEMENTATION ISSUES

Many of the approaches being considered have some "cons" associated with them. In order to effectively implement those approaches which are recommended, the cons must be adequately addressed. Input is being sought, pointing out some of the possible implementation issues which may be specific to a particular food fortification option:

Example of some potential implementation issues:

- Will this approach require a substantial educational effort; will it have a large effect on nutrition guidance systems such as Canada's Food Guide to Healthy Eating?
- Will implementation of this approach be complex?
- Is it overly complex to interpret or is the meaning unclear?
- Will it be difficult to enforce?
- Will it need intensive dietary intake monitoring?
- Will it result in health risks which are unacceptable or unmanageable?

APPENDIX A

REVIEW OF HEALTH CANADA'S POLICIES CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS

TIME LINES

Task	Date
Phase I - Define Scope, Prepare Draft Action Plan • Communicate plans for Policy Review to stakeholders • Establish Terms of Reference for External Advisory Panel • Invite nominees for External Advisory Panel	Winter 1997
Phase II - Establish External Advisory Panel	January 31, 1998
Phase III - Identify and Define Issues • Prepare Background Paper for Issue Identification and distribute to interested parties (post on website) • Consult with interested parties to define issues (facilitated 1 day open workshop) • Prepare and distribute report of above to participants and other interested parties (post on web)	 March 18, 1998 March 27, 1998 May 22, 1998
Phase IV - Analyze Issues • Analyse issues and potential policy options based on outcomes of March 27th Consultation Workshop and input from EAP • Prepare background paper for evaluation of potential food fortification approaches and distribute to interested parties (post on web site) • Consultation workshop to evaluate potential food fortification approaches • Prepare and distribute report of above to participants and other interested parties	 June 24-25, 1998 Sept. 14-15, 1998 November 13, 1998 November 23-25, 1998 January 31, 1999
Phase V - Recommend Solutions(s) • Evaluate potential solutions/policy options • Identify preferred solution/policy option • Publish policy options and preferred solution/policy option for review and comment	 March 15, 1999
Phase VI - Implementation	Begin June 1, 1999

APPENDIX B

REVIEW OF HEALTH CANADA'S POLICIES CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS INTERNAL GOVERNMENT WORKING GROUP - MEMBER LIST

Dr. Mary L'Abbé, Chair
Head, Micronutrients Section
Bureau of Nutritional Sciences
Banting Research Centre, 3-W
A.L. 2203C
Tunney's Pasture
Ottawa, ON K1A 0L2
tel: 957-0924; fax: 941-6636
email: Mary_L'Abbe@hc-sc.gc.ca

Ms. Sarah Conly
Nutrition Evaluation Division
Bureau of Nutritional Sciences
Banting Research Centre, 3-W
A.L. 2203A
Tunney's Pasture
Ottawa, ON K1A 0L2
tel: 957-0940; fax: 941-6636
email: Sarah_Conly@hc-sc.gc.ca

Dr. Margaret Cheney
Chief, Nutrition Evaluation Division
Bureau of Nutritional Sciences
Banting Research Centre, 3-W
A.L. 2203A
Tunney's Pasture
Ottawa, ON K1A 0L2
tel: 957-0352; fax: 941-6636
email: Margaret_Cheney@hc-sc.gc.ca

Ms. Nora Lee
Nutrition Evaluation Division
Bureau of Nutritional Sciences
Banting Research Centre, 3-W
A.L. 2203A
Tunney's Pasture
Ottawa, ON K1A 0L2
tel: 957-1740; fax: 941-6636
email: Nora_Lee@hc-sc.gc.ca

Dr. Kevin Cockell
Nutrition Research Division
Bureau of Nutritional Sciences
Banting Research Centre, 3-W
A.L. 2203C
Tunney's Pasture
Ottawa, ON K1A 0L2
tel: 957-0923; fax: 941-6182
email: Kcockell@hc-sc.gc.ca

Ms. Pat Steele
Food Division
Food Inspection Directorate
Canadian Food Inspection Agency
59 Camelot Drive
Nepean, ON K1A 0Y9
tel: 952-8000 ext 3800
fax: 228-6611
email: psteele@em.agr.ca

Ms. Halina Cyr, Manager
Nutrition & Healthy Eating Unit
Health Promotion and Programs Branch
Room B1748, Jeanne Mance Building
A.L. 1917C
Tunney's Pasture
Ottawa, ON K1A 1B4
tel: 941-2627; fax: 941-2432
email: Halina_Cyr@hc-sc.gc.ca

Ms. Lydia Dumais
Nutrition & Healthy Eating Unit
Health Promotion and Programs Branch
Room B1748, Jeanne Mance Building
A.L. 1917C
Tunney's Pasture
Ottawa, ON K1A 1B4
tel: 941-2627; fax: 941-2432
email: Lydia_Dumais@hc-sc.gc.ca

Dr. Brian Gillespie
Therapeutic Products Directorate
Room D272
Finance Building
A.L. 0202D2
Ottawa, ON K1A 1B6
tel: 954-6740; fax: 954-6511
email: Brian_Gillespie@hc-sc.gc.ca

REVIEW OF HEALTH CANADA'S POLICIES CONCERNING THE ADDITION OF VITAMINS AND MINERALS TO FOODS EXTERNAL ADVISORY PANEL - MEMBER LIST

Ms. Lise Bertrand
Santé Québec
Direction de la Santé Publique
Région Montréal-Centre
4835, rue Christophe-Colomb
Montréal, Québec H2J 3G8
tel: (514) 528-2400 ext 3469
fax: (514) 528-2512
email: lbertran@santepub-mtl.qc.ca

Dr. William Bettger
Dept. of Nutritional Sciences
University of Guelph
Guelph, ON N1G 2W1
tel: (519) 824-4120 ext 3747
fax: (519) 763-5902
email: wbettger.ns@aps.uoguelph.ca

Dr. Richard Black
Director, Scientific & Regulatory Affairs
Nestle Canada Inc.
25 Shepherd Avenue
North York, ON M2N 6S8
tel: (416) 218-2822; fax: (416) 218-2623
email: rblack@nestle.ca

Dr. Laurie Chan
Assistant Professor
CINE, McGill University
21, 111 Lakeshore Road
Ste-Anne-de-Bellevue, PQ H9X 3V9
tel: (514) 398-7765; fax: (514) 398-1020
email: chan@agradm.lan.mcgill.ca

Ms. Karen Cooper
Provincial Nutritionist
Saskatchewan Health
Programs Branch
3475 Albert Street
Regina, SK S4S 6X6
tel: (306) 787-3079; fax: (306) 787-3823
email: kcooper@health.gov.sk.ca

Dr. Loretta DiFrancesco
Senior Manager
Nutrition Research & Regulatory Development
Kellogg Canada Inc.
6700 Finch Avenue West
Etobicoke, ON M9W 5P2
tel: (416) 675-5324; fax:(416) 675-5211
email: loretta.difrancesco@kellogg.com

Dr. Guylaine Ferland
Université de Montreal
2405 Côte Ste. Catherine
C.P. 6128, Succ. 'A'
Montréal, Québec H3C 3J7
tel: (514) 343-7167; fax: (514) 343-7395
email: ferlandg@ere.umontreal.ca

Ms. Doris Gillis
Public Health Services
Eastern Health Region
Suite 200, 23 Bay Street
Antigonish, NS B2G 2G7
tel: (902) 863-3270; fax (902) 863-7476
email: d.gillis@ns.sympatico.ca

Ms. Rhea Joseph
Community Health Consultant
8870 - 213 Street
Langley, BC V1M 1Z3
tel: (604) 888-4858; fax: (604) 888-3468
email: rjoseph@axionet.com

Ms. Anne Kennedy
Nutrition Program Manager
Canadian Egg Marketing Agency
320 Queen Street
Suite 1900
Ottawa, ON K1R 5A3
tel: (613) 238-2514 ext 264
fax: (613) 238-1967
email: annek@canadaegg.ca

Dr. Valerie Tarasuk
Assistant Professor
Department of Nutritional Sciences
Faculty of Medicine
Room 316, 150 College Street
University of Toronto
Toronto, ON M5S 3E2
tel: (416) 978-0618; fax: (416) 978-5882
email: valerie.tarasuk@utoronto.ca

Dr. Stan Zlotkin
Hospital for Sick Children
555 University Avenue
Toronto, ON M5G 1X8
tel: (416) 813-6176; fax: (416) 813-4972

email: zlotkin@sickkids.on.ca

Foods to Which Vitamins, Mineral Nutrients and Amino Acids May be Added - Sorted by Reason for Addition

(*Food and Drug Regulations*, Adapted from Table D.03.002)

(As of June, 1998)

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	Pertinent Section of the Regulations
I. Restoration		
Flour, white flour, enriched flour or enriched white flour	Thiamine, riboflavin, niacin, vitamin B_6, *d*-pantothenic acid, iron and magnesium	B.13.001
Breakfast cereals	Niacin, vitamin B_6, folic acid, pantothenic acid, magnesium, and zinc	B.13.060
Alimentary pastes	Thiamine, riboflavin, niacin or niacinamide, pantothenic acid, vitamin B_6, iron, magnesium	B.13.052
Pre-cooked rice	Thiamine, niacin, vitamin B_6, folic acid, pantothenic acid, iron	B.13.010.1
Corn meal	Thiamine, riboflavin, niacin, iron	IMA, Nov. 1997
Skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, skim milk, partly skimmed milk, skim milk powder	Vitamin A	Division B.8 (various)
Evaporated skim milk, concentrated skim milk, evaporated partly skimmed milk, concentrated partly skimmed milk	Vitamin A	B.08.011-.012
Partly skimmed goat's milk, skimmed goat's milk, partly skimmed goat's milk powder, skimmed goat's milk powder	Vitamin A	B.08.029(2)
Evaporated partly skimmed goat's milk, evaporated skimmed goat's milk	Vitamin A	B.08.029(4)
Processed liquid whole egg, dried whole egg, frozen whole egg, liquid yolk, dried yolk, frozen yolk, liquid egg white, (liquid albumen), dried egg white (dried albumen), frozen egg white (frozen albumen), liquid whole egg mix, dried whole egg mix, frozen whole egg mix, liquid yolk mix, dried yolk mix, frozen yolk mix	Vitamin A, Vitamin D, Vitamin E, thiamine, riboflavin, niacin, vitamin B_6, folacin, vitamin B_{12}, pantothenic acid, calcium, phosphorus, magnesium, potassium, iron, zinc	B.22.038
Margarine and other similar substitutes for butter	Vitamin E	B.09.016
Dehydrated potatoes	Vitamin C	Part D *

* **Part D** refers to sections D.01.009, D.01.010, D.01.011, and D.02.009 which are general regulations stating the minimum and/or maximum amounts of specific nutrients that must be present in certain foods if one of those nutrients is added. These are used where no specific amounts are stated elsewhere in the Regulations. Quantities are based on the Reasonable Daily Intake of the food (Schedule K of the Regulations).

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	Pertinent Section of the Regulations
II. Substitute Foods		
Infant formulas	Amino Acids -- alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine; Minerals -- calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc; Vitamins -- alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin K	B.25.054 and others
Simulated meat products, simulated poultry meat products, meat product extenders and poultry product extenders	Thiamine, riboflavin, niacin, pyridoxine, *d*-pantothenic acid, folic acid, vitamin B_{12}, iron, magnesium, potassium, zinc, copper, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, valine	B.14.073, B.14.085-.090 B.22.027-.029
Products simulating whole egg	Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin B_6, *d*-pantothenic acid, folic acid, vitamin B_{12}, alpha-tocopherol, calcium, iron, zinc, potassium	B.22.032
Margarine and other similar substitutes for butter	Vitamin A	B.09.016
Fruit nectars, vegetable drinks, bases and mixes for vegetable drinks and a mixture of vegetable juices	Vitamin C	Division B.11 (various)
Fruit-flavoured drinks that are sold as a substitute for fruit juice or as a breakfast drink	Vitamin C, folic acid, thiamine, iron, potassium	B.11.150
Bases, concentrates and mixes that are used for making fruit-flavoured drinks that are sold as a substitute for juice or as a breakfast drink.	Vitamin C, folic acid, thiamine, iron, potassium	B.11.151
Apple juice, reconstituted apple juice, grape juice, reconstituted grape juice, pineapple juice, reconstituted pineapple juice, apple and (naming the fruit) juice as described in section B.11.132, concentrated fruit juice except frozen concentrated orange juice	Vitamin C	Division B.11 (Various)
Plant-based beverages	Vitamin A, vitamin D, vitamin B_{12}, riboflavin, calcium, zinc, vitamin B_6, vitamin C, thiamin, niacin, folacin, pantothenic acid, phosphorus, potassium, magnesium	IMA, Nov. 1997.

* **Part D** refers to sections D.01.009, D.01.010, D.01.011, and D.02.009 which are general regulations stating the minimum and/or maximum amounts of specific nutrients that must be present in certain foods if one of those nutrients is added. These are used where no specific amounts are stated elsewhere in the Regulations. Quantities are based on the Reasonable Daily Intake of the food (Schedule K of the Regulations).

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	Pertinent Section of the Regulations
III. Fortification		
Flour, white flour, enriched flour or enriched white flour	Folic acid, calcium	B.13.001
Infant cereal products	Thiamine, riboflavin, niacin or niacinamide, calcium, phosphorus, iron, iodine	Part D *
Breakfast cereals	Thiamine, iron	B.13.060
Alimentary pastes	Folic acid	B.13.052
Corn meal	Calcium and folic acid	IMA, Nov. 1997
Margarine and other similar substitutes for butter	Vitamin D	B.09.016
Flavoured beverage mixes and bases recommended for addition to milk	Vitamin A, thiamine, niacin or niacinamide, vitamin C, iron	Part D *
Milk, milk powder, sterilized milk, (naming the flavour) milk, condensed milk	Vitamin D	Division B.8 (various)
Skim milk with added milk solids, partly skimmed milk with added milk solids, (naming the flavour) skim milk, (naming the flavour) partly skimmed milk, (naming the flavour) skim milk with added milk solids, (naming the flavour) partly skimmed milk with added milk solids, skim milk, partly skimmed milk, skim milk powder	Vitamin D	Division B.8 (various)
Evaporated milk	Vitamin C, vitamin D	B.08.010
Evaporated skim milk, concentrated skim milk, evaporated partly skimmed milk, concentrated partly skimmed milk	Vitamin C, vitamin D	B.08.011-.012
Table salt, table salt substitutes	Iodine	B.17.003
Goat's milk, goat's milk powder	Vitamin D	B.08.029(1)
Partly skimmed goat's milk, skimmed goat's milk, partly skimmed goat's milk powder, skimmed goat's milk powder	Vitamin D	B.08.029(2)
Evaporated goat's milk	Vitamins C, D, folic acid	B.08.029(3)
Evaporated partly skimmed goat's milk, evaporated skimmed goat's milk	Vitamins C, D, folic acid	B.08.029(4)
Mineral water, spring water, water in sealed containers, prepackaged ice	Fluorine	B.12.001

* **Part D** refers to sections D.01.009, D.01.010, D.01.011, and D.02.009 which are general regulations stating the minimum and/or maximum amounts of specific nutrients that must be present in certain foods if one of those nutrients is added. These are used where no specific amounts are stated elsewhere in the Regulations. Quantities are based on the Reasonable Daily Intake of the food (Schedule K of the Regulations).

COLUMN I Food	COLUMN II Vitamin, Mineral Nutrient or Amino Acid	Pertinent Section of the Regulations
IV. Special Purpose Foods		
Foods represented for use in a very low-energy diet	Vitamins - alpha-tocopherol, biotin, *d*-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D, vitamin K Minerals - calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc	B.24.303
Meal replacements and nutritional supplements	Minerals -- calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc Vitamins -- alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitamin B_{12}, vitamin C, vitamin D	B.24.200 B.24.201
Formulated liquid diets	Amino Acids -- alanine, arginine, aspartic acid, cystine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine; Minerals -- calcium, chloride, chromium, copper, iodine, iron, magnesium, manganese, molybdenum, phosphorus, potassium, selenium, sodium, zinc; Vitamins -- alpha-tocopherol, biotin, d-pantothenic acid, folic acid, niacin, riboflavin, thiamine, vitamin A, vitamin B_6, vitaminB_{12}, vitamin C, vitamin D, vitamin K	B.24.102
Ready breakfast, instant breakfast and other similar breakfast replacement foods however described	Vitamin A, thiamine, riboflavin, niacin or niacinamide, vitamin C, iron	B.01.053 and Part D*

* **Part D** refers to sections D.01.009, D.01.010, D.01.011, and D.02.009 which are general regulations stating the minimum and/or maximum amounts of specific nutrients that must be present in certain foods if one of those nutrients is added. These are used where no specific amounts are stated elsewhere in the Regulations. Quantities are based on the Reasonable Daily Intake of the food (Schedule K of the Regulations).

FOOD & DRUG DIRECTORATE
Department of National Health and Welfare
Ottawa, Canada

T.I.L. NO. 351
Date: April 28, 1971

To: All Food Manufacturers

Re: Proposed Guidelines for the Addition of Nutrients to Foods

Consumers customarily have relied on a varied diet of traditional foods to ensure an adequate intake of nutrients. Occasionally it has been necessary to add nutrients to certain foods to restore those lost in processing or to prevent nutritional deficiencies. During recent years increased interest has developed in new types of foods including snack foods, substitute foods and meal replacements, which may not have the nutrient content of traditional foods. Therefore, increased attention must be given to nutritional aspects of food standards. Accordingly, the Food and Drug Directorate has developed for discussion the following guidelines for the addition of nutrients to foods:

1. Vitamins, minerals and protein added to traditional foods should be present in amounts related to the purpose of the addition:

   a) to replace those nutrients lost in the course of good manufacturing practice if the amount originally present provided at least 10% of the daily requirement of these nutrients in a reasonable daily intake of the food. The amount added should compensate for that lost in processing.

   b) to correct a demonstrated deficiency of one or more of these nutrients in some segment of the population if such addition is the most effective means of correcting the deficiency. The amount should only be sufficient to correct the deficiency.

2. A food sold or used as a substitute for a traditional food that normally provides, in a reasonable daily intake of the food, at least 10% of the daily requirement of a nutrient (including calories) should contain an equivalent amount of that nutrient.

3. Foods sold or represented as meal replacements shall contain essential nutrients including calories in amounts related to the purpose of the meal, e.g., instant breakfasts and infant formulas.

4. Snack foods for which nutritional claims are made and which supply at least 200 calories in a reasonable daily intake, shall contain essential nutrients in proportion to their caloric content. No nutritional claims should be made for unfortified snack foods or fun-foods.

For these guidelines, the daily requirement of a nutrient will be based on the Canadian Dietary Standard where such exists. A detailed listing will be available in the near future. A table of Reasonable Daily Intakes of various foods was passed by P.C. 1971-356 of February 23, 1971, and published in the Canada Gazette, Part II, of March 10, 1971. These were issued in T.I.L. No. 347 of March 19, 1971.

The Directorate is aware that the principles outlined above will require amendment of present regulations. We will be pleased to receive views and suggestions concerning these guidelines before proceeding with the amendments.

orig. signed by:
R.A. Chapman,
Assistant Deputy Minister

SPECIAL PURPOSE FOODS

- Codex Alimentarius defines **Special Purpose Foods (SPFs)** in the General Principles for the Addition of Essential Nutrients to Foods as "foods that have been designed to perform a specific function, such as to replace a meal, which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use."

- Codex defines **Foods for Special Dietary Use (FSDUs)** in their General Standard for the Labelling and Claims for Prepackaged Foods for Special Dietary Uses as "those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist."

- Canada has regulations for FSDUs that define this category in a way very similar to the above (Division 24 of the Food and Drug Regulations). FSDUs include meal replacements, nutritional supplements, low sodium foods, gluten-free foods, formulated liquid diets and sugar-free foods. The Regulations control the composition of FSDUs by stating, "No person shall label, package, sell or advertise a food in a manner likely to create an impression that it is a food for special dietary use unless the food is..." This is followed by a list of foods including those mentioned above each showing, where applicable, the regulation in which it is defined. In the latter regulations, the compositional requirements for foods so represented are given.

- The general regulatory approach taken is that a product for a special dietary use must have on the label a statement of the type of diet it is intended for (e.g. sodium-restricted diet), a statement that describes the way the food is special (e.g. low sodium) and nutrition information about the content of core nutrients and additional relevant nutrients, and it must meet appropriate compositional criteria. No pre-market notification is required for FSDUs. However, for meal replacements, formulated liquid diets and foods represented for use in a very low energy diet, there is a "stop sale" provision that requires that a manufacturer cease to sell the product as soon as they are requested by the Director (i.e. the Assistant Deputy Minister of HPB) to submit evidence. This is evidence with respect to whether the product is suitable to be used as a sole source of nutrition when used as intended. Also, formulated liquid diets may not be advertised to the general public.

- ParNuts, or **foodstuffs intended for Particular Nutritional Uses**, is a food category created by the Council of European Communities in a 1989 directive (89/398/EEC). From the definition, these products appear to be similar to Foods for Special Dietary Use (see above) except that they include infant formulas and other foods for infants and young children in good health. The foods for which individual standards were to be issued include infant formulas, dietary foods for special medical purposes, low-energy foods for weight control, gluten-free foods, foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, etc.

- Codex also defines **Foods for Special Medical Purposes**. These are defined as a category of FSDUs that are "specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other food for special dietary uses, or by a combination of the two." Canada's formulated liquid diets, also regulated in Division 24, serve a similar purpose.

FOOD AND NUTRITION BOARD, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES
DIETARY REFERENCE INTAKES: RECOMMENDED LEVELS FOR INDIVIDUAL INTAKE

Life-Stage Group	Calcium (mg/d)	Phosphorus (mg/d)	Magnesium (mg/d)	Vitamin D (μg/d)[a,b]	Fluoride (mg/d)	Thiamin (mg/d)	Riboflavin (mg/d)	Niacin (mg/d)[c]	Vitamin B_6 (mg/d)	Folate (μg/d)[d]	Vitamin B_{12} (μg/d)	Pantothenic Acid (mg/d)	Biotin (μg/d)	Choline[e] (mg/d)
Infants														
0 - 6 mo	210*	100*	30*	5*	0,01*	0,2*	0,3*	2*	0,1*	65*	0,4*	1,7*	5*	125*
7 - 12 mo	270*	275*	75*	5*	0,5*	0,3*	0,4*	4*	0,3*	80*	0,5*	1,8*	6*	150*
Children														
1 - 3 yr	500*	**460**	**80**	5*	0,7*	**0,5**	**0,5**	**6**	**0,5**	**150**	**0,9**	2*	8*	200*
4 - 8 yr	800*	**500**	**130**	5*	1*	**0,6**	**0,6**	**8**	**0,6**	**200**	**1,2**	3*	12*	250*
Males														
9 - 13 yr	1300*	**1250**	**240**	5*	2*	**0,9**	**0,9**	**12**	**1,0**	**300**	**1,8**	4*	20*	375*
14 - 18 yr	1300*	**1250**	**410**	5*	3*	**1,2**	**1,3**	**16**	**1,3**	**400**	**2,4**	5*	25*	550*
19 - 30 yr	1000*	**700**	**400**	5*	4*	**1,2**	**1,3**	**16**	**1,3**	**400**	**2,4**	5*	30*	550*
31 - 50 yr	1000*	**700**	**420**	5*	4*	**1,2**	**1,3**	**16**	**1,3**	**400**	**2,4**	5*	30*	550*
51 - 70 yr	1200*	**700**	**420**	10*	4*	**1,2**	**1,3**	**16**	**1,7**	**400**	**2,4**[f]	5*	30*	550*
>70 yr	1200*	**700**	**420**	15*	4*	**1,2**	**1,3**	**16**	**1,7**	**400**	**2,4**[f]	5*	30*	550*
Females														
9 - 13 yr	1300*	**1250**	**240**	5*	2*	**0,9**	**0,9**	**12**	**1,0**	**300**	**1,8**	4*	20*	375*
14 - 18 yr	1300*	**1250**	**360**	5*	3*	**1,0**	**1,0**	**14**	**1,2**	**400**[g]	**2,4**	5*	25*	400*
19 - 30 yr	1000*	**700**	**310**	5*	3*	**1,1**	**1,1**	**14**	**1,3**	**400**[g]	**2,4**	5*	30*	425*
31 - 50 yr	1000*	**700**	**320**	5*	3*	**1,1**	**1,1**	**14**	**1,3**	**400**[g]	**2,4**	5*	30*	425*
51 - 70 yr	1200*	**700**	**320**	10*	3*	**1,1**	**1,1**	**14**	**1,5**	**400**	**2,4**[f]	5*	30*	425*
>70 yr	1200*	**700**	**320**	15*	3*	**1,1**	**1,1**	**14**	**1,5**	**400**	**2,4**[f]	5*	30*	425*
Pregnancy														
≤ 18 yr	1300*	**1250**	**400**	5*	3*	**1,4**	**1,4**	**18**	**1,9**	**600**[h]	**2,6**	6*	30*	450*
19 - 30 yr	1000*	**700**	**350**	5*	3*	**1,4**	**1,4**	**18**	**1,9**	**600**[h]	**2,6**	6*	30*	450*
31 - 50 yr	1000*	**700**	**360**	5*	3*	**1,4**	**1,4**	**18**	**1,9**	**600**[h]	**2,6**	6*	30*	450*
Lactation														
≤ 18 yr	1300*	**1250**	**360**	5*	3*	**1,5**	**1,6**	**17**	**2,0**	**500**	**2,8**	7*	35*	550*
19 - 30 yr	1000*	**700**	**310**	5*	3*	**1,5**	**1,6**	**17**	**2,0**	**500**	**2,8**	7*	35*	550*
31 - 50 yr	1000*	**700**	**320**	5*	3*	**1,5**	**1,6**	**17**	**2,0**	**500**	**2,8**	7*	35*	550*

NOTE: This table presents Recommended Dietary Allowances (RDAs) in bold type and Adequate Intakes (AIs) in ordinary type followed by an asterisk (*). RDAs and AIs may be used as goals for individual intake. RDAs are set to meet the needs of almost all (97 to 98 percent) individuals in a group. For healthy breastfed infants, the AI is the mean intake. The AI for other life-stage and gender groups is believed to cover needs of all individuals in the group, but lack of data or uncertainty in the data prevent being able to specify with confidence the percentage of individuals covered by this intake.

[a] As cholecalciferol. 1 μg cholecalciferol = 40 IU vitamin D.

[b] In the absence of adequate exposure to sunlight.

[c] As niacin equivalents (NE). 1 mg of niacin = 60 mg of tryptophan; 0-6 months = preformed niacin (not NE).

[d] As dietary folate equivalents (DFE). 1 DFE = 1 μg food folate = 0.6 μg of folic acid (from fortified food or supplement) consumed with food = 0.5 μg of synthetic (supplemental) folic acid taken on an empty stomach.

[e] Although AIs have been set for choline, there are few data to assess whether a dietary supply of choline is needed at all stages of the life cycle, and it may be that the choline requirement can be met by endogenous synthesis at some of these stages.

[f] Because 10 to 30 percent of older peop.e may malabsorb food-bound B_{12}, it is advisable for those older than 50 years to meet their RDA mainly by consuming foods fortified with B_{12} or a supplement containing B_{12}.

[g] In view of evidence linking folate intake with neural tube defects in the fetus, it is recommended that all women capable of becoming pregnant consume 400 μg of synthetic folic acid from fortified foods and/or supplements in addition to intake of food folate from a varied diet.

[h] It is assumed that women will continue consuming 400 μg of folic acid until their pregnancy is confirmed and they enter prenatal care, which ordinarily occurs after the end of the preconceptional period - the critical time for formation of the neural tube.

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DIETARY REFERENCE INTAKES
Background Information

- The Dietary Reference Intakes (DRIs) are a set of scientifically based nutrient reference values that will be used by government agencies, non governmental health agencies and health professionals in policy and program development. For instance, the DRIs will be used in the assessment of individual's or group's nutrient intakes; the planning of feeding programs; development of nutrition education materials; formation of policy decisions on the fortification of foods, and formulation of supplements and special dietary foods.

- The development of the DRIs is under way at this time. They are being established by Canadian and American scientists, through a review process overseen by the U.S. National Academy of Science's Food and Nutrition Board (FNB).

- Health Canada is participating in the U.S. review of nutrient requirements. Health Canada has reviewed and made recommendations on nutrient requirements on a periodic basis since 1938, the last update being in 1990 as part of **Nutrition Recommendations: The Report of the Scientific Review Committee**. By 1994, it became clear that an update would be needed soon and, since the Food and Nutrition Board of the National Academy of Sciences was beginning a consultation process on the review of the Recommended Dietary Allowances, Health Canada decided that participating in the U.S. review would offer several advantages to Canada.

- The Food and Nutrition Board Dietary Reference Intakes will ultimately replace the Canadian RNIs. The aim of having American and Canadian scientists working together on this review was to achieve a set of harmonized dietary reference values for both countries.

- Like the current Recommended Nutrient Intakes (RNIs), the evidence considered in determining the DRIs includes, where available, evidence that relates nutrients to the prevention of disease and developmental disorders along with more traditional evidence of sufficient nutrient intake. On the other hand, evidence concerning the use of nutrients in the mitigation or cure of a disease or disability was not considered because that was beyond the scope of the project.

- Unlike the current RNIs which are a single number, Dietary Reference Intakes (DRIs) are a set of numbers for different uses. These are Estimated Average Requirements (EAR), Recommended Dietary Allowances (RDA), Adequate Intakes (AI) and Tolerable Upper Intake Levels (UL). These are defined as follows:

Estimated Average Requirement (EAR): the daily intake value estimated to meet the requirement, as defined by the specified indicator of adequacy, in 50% of the individuals in a life-stage or gender group. At this level of intake, the other 50% of a specified group would not have its nutritional needs met.

Recommended Daily Allowance (RDA): the dietary intake level that is sufficient to meet the daily nutrient requirements of almost all individuals (97-98%) in a specific life-stage and gender group (If an EAR is established, an RDA is established).

Adequate Intake (AI): if sufficient scientific evidence is not available to calculate an EAR, the reference value established is an AI. The AI is based on observed or experimentally determined approximations of the average nutrient intake, by a defined population or subgroup, that appears to sustain a defined nutritional state, such as normal circulating nutrient values or growth. Contemporary concepts of reduction in disease risk are incorporated into the derivation of the AI. (No RDA is established when only an AI is available.)

Tolerable Upper Intake Level (UL): is the highest level of daily nutrient intake that is likely to pose no risks or adverse effects to almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases. The term tolerable intake was chosen to avoid implying a possible beneficial effect. The term connotes a level of intake that can, with high probability, be tolerated biologically. The UL is not intended to be a recommended level of intake. There is no established benefit for healthy individuals if they consume nutrient intakes above the RDA or AI. UL s are based on the total intake of a nutrient from food, water and supplements if adverse effects have been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from those sources only, not on total intake. The UL applies to chronic daily use. For many nutrients, there may be insufficient data on which to develop a UL. This does not mean that there is no potential for adverse effects resulting from high intake. When data about adverse effects are extremely limited, extra caution may be warranted.

Note that Dietary Reference Intakes are reference values for healthy populations only.

For more information, please visit the Food Directorate web site at:
www.hc-sc.gc.ca/datahpb/datafood, and look for Nutritional Sciences, Nutrition and Dietary Guidance, Dietary Reference Intakes.

APPENDIX I

Summary of type of regulatory or legislative controls on addition of vitamins and minerals to ordinary foods. Results of 1994 Survey Conducted by the Nordic Council of Ministers [1]

Country	Legislation/ Regulations on nutrient addition	Legislation / Regulation based on:[2]				Remarks
		General permission	Individual Authorization	Notification	Free	
Austria	No (except salt)				X	Nutrient addition is free as long as no health hazards exist and labelling does not mislead or deceive
Belgium	Yes	X		X		Nutrient addition allowed for all foods but notification is needed. Minimum and maximum final levels of nutrients in foods are defined
Denmark	Yes	X*	X+			*For flours, oatcakes, cereals, juices ; +For everything else
Finland	Yes	X*	X+			*For margarines; +For everything else. Moving toward General Permission.
Germany	Yes	X				Addition of named vitamins permitted without limitations. For vitamins A and D, maximum levels given. Permissible nutrient compounds listed.
Greece	Yes	X*	X+			*For margarines, fat emulsions, salt; +For everything else
Iceland	Yes	X*		X+		*For margarines; +For everything else. New regulations being drafted
Italy	No		X			Nutrient addition allowed only if approved by Ministry of Health
Luxembourg	No				X	Nutrient levels should not be high enough to exceed RDI
Netherlands	Yes					Nutrient addition prohibited except compulsory additions to margarines and breadsalt and optional addition to salt but regulations changing: more liberal
Norway	Yes	X*	X+			*For margarines, butter, oils, salt and goat whey cheese; +For everything else
Sweden	Yes	X*	X+			*For fat reduced milk, oils, salt, flours, pasta, +For everything else
Switzerland	Yes (for vitamins)	X				Addition of named vitamins allowed to all foods, maximum limits set
UK	Yes	X			X	Addition not restricted, provided not injurious to health
Australia	Yes	X				Foods, allowed nutrients and their levels specified
Canada	Yes	X				Foods, allowed nutrients and their levels specified
USA	Yes	X*			X+	*Food standards and food additive regulations control what nutrients may be added. Substitute foods must be made nutritionally equivalent to food replaced or else food must be labelled "imitation". +Unstandardized foods

1. Adapted from "Addition of Nutrients to Foods - Principles and Practices", published by the Nordic Council of Ministers, Copenhagen, TemaNord 1995:643; and D.P. Richardson, The addition of nutrients to foods, Proc. Nutr. Soc., 56:807-825, 1997.

2. *General Permission*: Where nutrient addition is regulated by legislation which specifies the foods and/or nutrients permitted. Levels of permitted nutrients might also be specified.
Individual authorization: Where nutrient addition is not permitted unless permission is specifically applied for from the authorities.
Notification: Where nutrient addition is permitted but notification is required.
Free nutrient addition: where there are no authorization procedures nor restrictions governing nutrient addition to foods, or no legislation

CANADA'S OBLIGATIONS UNDER INTERNATIONAL TRADE AGREEMENTS

- The Codex Alimentarius Commission (Codex) was created in 1962 by the Food and Agriculture Organization of the United Nations and the World Health Organization as an intergovernmental body with the objectives of protecting the consumers' health and facilitating international trade in food. Codex is responsible for establishing standards, guidelines, codes of practice and other advisory texts concerning the safety and quality of foods. Canada is one of over 160 member countries of Codex.

- Codex standards, guidelines and recommendations are elaborated for voluntary adoption by countries. These texts are also used as a reference in international trade by the World Trade Organization (WTO) under the Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). Codex standards are not directly referenced in the TBT; they are in the SPS.

- The SPS Agreement provides that WTO Members should use international standards where such standards meet that countries level of protection, and specifically cites three international standards setting organizations, with Codex being the reference for food standards. Under the SPS, countries which establish requirements that are more stringent than the standards, guidelines and recommendations developed by Codex may be required to provide a justification for their higher standards if a trade dispute arises. The WTO does not have the authority to require countries to adopt Codex texts, but does arbitrate trade disputes which may result in one of the parties modifying their measures, using a science-based justification or providing compensation if that party cannot scientifically justify a more stringent requirement which it continues to use. The methodologies and approaches used by Canada are well accepted internationally and frequently used in discussions by international standards setting bodies.

- The scopes of the SPS and TBT agreements differ. The SPS Agreement covers measures whose purpose is to protect human health, animal health and plant health. More specifically, it covers measures designed to protect human health from risks arising from food additives, contaminants (including pesticides, veterinary drugs and extraneous matter), toxins or disease-causing organisms in food and beverages, and to protect animals and plants from pests or diseases. The SPS Agreement does not cover public health measures in the broad sense neither does it include issues relating to nutrition and nutrition labelling.

- The TBT Agreement covers all other food issues, including nutrition and nutrition labelling. Under this agreement, where technical regulations are required and international standards exist, members are expected to use such standards except where they would be ineffective for the fulfilment of a legitimate objective including national security, prevention of deceptive practices, protection of human health or safety, animal or plant health or the environment.

- The two Agreements have some common elements, including basic obligations for non-discrimination and similar requirements for the advance notification of proposed measures and the creation of information offices. For example, both Agreements encourage the use of international standards. Under the TBT Agreement however, governments may decide that international standards are not appropriate for other reasons, including fundamental technological problems or geographical factors and may introduce regulations when necessary to meet a number of objectives, such as national security or the prevention of deceptive practices.

- The provisions of the NAFTA Agreements in SPS and TBT areas are very similar to those of the TBT and SPS Agreements under the WTO.

- More information can be found on the Web at <<*www.wto.org*>>

CLARIFICATION OF TERMS: TOTAL DIET and TOTAL EXPOSURE

- **Total Diet** incorporates the wide range of foods that are part of Canadian food consumption patterns. It includes the four food groups (grain products, vegetables & fruit, milk products, meat & alternatives), plus an 'other foods' group covering a wide range of dietary items and beverages that contribute to taste and enjoyment in eating. The value of increased food variety in ensuring essential nutrient adequacy and decreasing the risk of food toxicity (health-adverse factors in food are generally diluted when the foods eaten are varied) has been understood for some time. The total diet approach integrates current nutrition recommendations into food selection suggestions that meet the objectives for both nutrient adequacy and moderation of food consumption relative to risk for specific diet-related chronic diseases (Technical Group for the Review of Canada's Food Guide, 1990). The focus on foods recognizes the beneficial aspects of foods beyond the known essential vitamins and minerals (e.g. fibre, phytochemicals, or other beneficial components of foods).

- **Total Exposure** is used to denote total oral exposure of nutrients from all sources. This term includes ingestion of nutrients from foods (as naturally-occurring nutrients, food additives or food fortificants), water and as a component of supplements or over-the-counter drugs. In the derivation of ULs, the US National Academy of Sciences, Food and Nutrition Board based the DRIs on total intake of nutrients from these sources (Chapter 3, Development of Tolerable Upper Intake Levels, Dietary Reference Intakes for B Vitamins, 1998).

DEFINITION OF TOLERABLE UPPER INTAKE LEVELS (UL) and CRITICAL END POINTS USED IN DERIVATION OF ULs

Definition of Tolerable Upper Intake Level (UL)

The Tolerable Upper Intake Level (UL) is the highest level of daily nutrient intake that is likely to pose no risks or adverse effects to almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases. The term tolerable intake was chosen to avoid implying a possible beneficial effect. The term tolerable is chosen because it connotes a level of intake that can, with high probability, be tolerated biologically. The UL is not intended to be a recommended level of intake. There is no established benefit for healthy individuals if they consume nutrient intakes above the RDA or AI. ULs are based on the total intake of a nutrient from food, water and supplements if adverse effects have been associated with total intake. However, if adverse effects have been associated with intake from supplements or food fortificants only, the UL is based on nutrient intake from those sources only, not on total intake. The UL applies to chronic daily use. For many nutrients, there may be insufficient data on which to develop a UL. This does not mean that there is no potential for adverse effects resulting from high intake. When data about adverse effects are extremely limited, extra caution may be warranted. [1]

Critical End Points Used in Derivation of ULs

Note: UF = Uncertainty Factor used in the derivation of ULs. In general, small UFs (close to 1) are used if little population variability is expected for the adverse effect. (From NAS, IOM, FNB, 1998 p. 3-10).

Calcium (UF used = 2)

Milk Alkali Syndrome - hypercalcemia, renal insufficiency with or without alkalosis; progressive renal failure resulting in deposition of calcium in soft tissues including the kidney (nephrocalcinosis) with a potentially fatal outcome.

Phosphorus (UF used = 2.5)

Intake associated with the upper boundary of adult normal values of serum Pi; no reports of adverse effects clearly attributable to high phosphorus intakes.

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[1]Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline. (Prepublication Copy). Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, 1998, Chapter 3. *(http://www.nap.edu/readingroom/)*

Magnesium (UF used = 1)

No adverse effects associate with naturally occurring Mg in foods have been reported. Derived from osmotic diarrhea effects of various magnesium salts (non food) used for pharmacologic purposes.

Vitamin D (UF used = 1.2)

Based on intake of vitamin D which results in hypercalcemia which is associated with polyuria and polydipsia, and prolonged exposure can result in soft tissue calcification of kidney, blood vessels, heart and lungs, CNS involvement, anorexia, nausea and vomiting and decreased renal function.

Fluoride (UF used = 1)

Based on the cosmetic effect of moderate enamel fluorosis in susceptible age groups without adverse functional effect.

Thiamin

No reports of adverse effects; no UL derived. Supplements up to 50 mg/day widely available without prescription but no systematic examination of effects.

Riboflavin

No adverse effects with consumption from food or supplements have been reported although the potential for adverse effects has not been systematically evaluated. No UL derived.

Niacin (UF used = 1.5)

No adverse effects reported from consumption of naturally occurring niacin in foods, therefore UL for niacin is derived from evidence concerning intake of niacin as a supplement, food fortificant, or pharmacologic agent. Critical adverse effect used is flushing which is a burning, tingling, and itching sensation, as well as a reddened flush primarily on the face, arms, and chest.

Vitamin B_6 (UF used = 2)

Derived from large oral supplement doses of pyridoxine associated with sensory neuropathy and dermatological lesions.

Folate (UF = 5)

No adverse effects have been associated with the consumption of excess folate from foods, but adverse effects associated with synthetic folic acid have been observed. UL derived from B_{12} deficient patients receiving oral folic acid resulting in a progression of neurological disorders.

Vitamin B_{12} (Cobalamin)

No adverse effects have been associated with excess B_{12} intake from food and supplements in healthy individuals. Insufficient evidence to derive a UL.

Pantothenic acid

No reports of adverse effects of oral pantothenic acid have been found. Since no adverse effects have been associated with high intakes of pantothenic acid, the risk due to expose is most likely low.

Biotin

No reported adverse effect of biotin in humans and animals were found; several studies involving high biotin intakes reported no adverse effects.

Choline (UF used = 2)

The critical effect for determining the UL for choline is based on a single case of hypotension and several other studies involving cholenergic effects and fishy body odour. Individuals with the following conditions may be at risk of adverse effects with choline intakes at the UL: trimethylaminuria (fish odour syndrome), renal disease, liver disease, depression, and Parkinson's disease.

RISK MANAGEMENT

Risk vs Safety:

Like all chemical agents, nutrients can produce adverse health effects and it is not possible to identify a single "risk free" or "safe" intake level for a nutrient that can be applied with certainty to all members of a population. To evaluate the effectiveness or safety, need an estimate of exposure dose. The required precision of that estimate will depend on the margin of safety of the nutrient. Because there is no single scientifically definitive distinction between "safe" and "unsafe" exposures, this section should more correctly be termed Risk Management.

What is Risk Management:

Risk may be defined in general terms, as a measure of the harm to human health that results from being exposed to an agent, substance, process, or product (or in other words, a hazard) together with the likelihood that the harm will occur. Agencies that are involved in health protection often use a formalized process for assessing and managing health risks. This process generally involves identifying specific hazards, estimating the associated level of risk, developing and analysing potential options for managing the risk, selecting and implementing a specific risk management strategy, and monitoring and evaluating the impact of this strategy[1]. Risk management decisions depend on risk assessments, but also involve the public health significance of the risk, the technical feasibility of achieving various degrees of risk control, and the economic and social costs of this control[2].

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[1] Risk Management in Health Protection (Draft), Revised HPB Risk Management Framework, Phase II Report, 1997. (p. 1)

[2] Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B_6, Folate, Vitamin B_{12}, Pantothenic Acid, Biotin, and Choline. (Prepublication Copy). Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, 1998. (p. 3-2)